IN THE UNITED DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, et al., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**MDL NO. 3026** **Master Docket No.: 1:22-cv-00071** **Judge: Hon. Rebecca R. Pallmeyer**
This Document Relates to: ZAIRA RIOS and MARTIN RIOS, as husband and wife, individually, and as the representatives to the Estate of THEODORE RIOS, deceased, Plaintiffs, vs. ABBOTT LABORATORIES, INC., ABBOTT LABORATORIES, and MEAD JOHNSON & COMPANY, LLC a/k/a MEAD JOHNSON NUTRITION COMPANY Defendants. Case No.:	**COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs Zaira Rios and Martin Rios, as husband and wife, individually and as the representatives to the Estate of Theodore Rios, deceased (collectively, "Plaintiffs") bring this Complaint and Demand for Jury Trial (the "Complaint") against Defendants Abbott Laboratories, Inc., Abbott Laboratories, and Mead Johnson & Company, LLC a/k/a Mead Johnson Nutrition Company (collectively, "Defendants"). Plaintiffs allege the following upon personal knowledge as to Plaintiffs' own acts and experiences and upon information and belief, including investigation conducted by Plaintiffs' attorneys, as to all other matters:

NATURE OF THE ACTION

1. This action arises out of the injuries suffered by premature infant Theodore Rios ("Baby Theodore") who was given Defendants' cow's milk-based infant feeding products. Defendants' products caused Baby Theodore to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result, Baby Theodore was catastrophically injured, resulting in his death and harm to Plaintiffs.

2. Plaintiffs bring these causes of action against Defendants to recover for injuries that are the direct and proximate result of Baby Theodore's consumption of Defendants' unreasonably dangerous cow's milk-based infant feeding products.

PARTIES

3. Baby Theodore was born prematurely at LAC + USC Medical Center in Los Angeles, California on September 3, 2021. He died on November 22, 2021, after developing NEC. Baby Theodore developed NEC after being fed Similac Human Milk Fortifier while in the Newborn Intensive Care Unit ("NICU") at LAC + USC Medical Center in Los Angeles, California. At all times material hereto, Baby Theodore was domiciled in and a citizen of the State of California.

4. Plaintiffs, Zaira Rios and Martin Rios, are the biological parents of Baby Theodore, (hereinafter "Baby Theodore's Parents"), they are domiciled in and citizens of the State of California, and reside in Los Angeles County, California. Baby Theodore's Parents bring this action for the wrongful death of Baby Theodore, on behalf of the Estate and the individual survivors thereof.

5. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, "Mead") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

6. Defendants Abbott Laboratories, Inc. and Abbott Laboratories ("Abbott") are corporations, incorporated under the laws of the State of Illinois. Their principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant feeding products and markets many of its products under the "Similac" brand name.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiffs and the Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.00.

8. Venue of this action is proper in this Court pursuant to 28 U.S.C. §§1391 (a) and (b) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this judicial district. Venue is also proper under 18 U.S.C. §1965 (a) because Defendants are headquartered in this District and transacts substantial business in this District.

9. This Court has personal jurisdiction over Defendants because Defendants are headquartered in Chicago, Illinois.

FACTUAL ALLEGATIONS

Theodore Rios NEC Diagnosis

10. Theodore Rios was born prematurely at LAC + USC Medical Center in Los

Angeles, California on September 3, 2021.

11. Baby Theodore was fed Similac and/or Similac products, cow's milk-based products, shortly after his birth.

12. Shortly after first ingesting Defendants' products, Baby Theodore developed NEC.

13. Baby Theodore ultimately succumbed to his injuries after ingesting Defendants' products on November 22, 2021.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed often leading to death. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was ***six to ten*** times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and ***three times*** more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was ***20 times more common*** in those only fed cow's milk formula than in those fed breast milk.

17. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were ***90% less likely*** to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

18. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

19. A Surgeon General report, *The Surgeon General's Call to Action to Support Breastfeeding*, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are ***138% more likely*** to develop NEC.

20. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that ***all*** premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

21. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC ***21% of the time***.

22. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a

diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives to Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and milk fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

25. Defendants' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based

diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

27. At the time Baby Theodore was fed Defendants' products, the science clearly demonstrated to Defendants that these products cause and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific consensus that Defendants' cow's milk-based products present a dire threat to the health and development of preterm infants, Defendants have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, Defendants have continued to sell their unreasonably dangerous products to unsuspecting parents and healthcare providers, generating huge profits as a result.

Defendants' False And Misleading Marketing Regarding Cow's Milk Based Infant Products

29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to Baby Theodore's birth.

30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that Defendants' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. *None* of Defendants' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

31. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

32. Undoubtedly aware of the impact of their advertising, Defendants, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent $4.48 billion on marketing and promotion in 2014 alone.

33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

34. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, Defendants' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

35. For example, Abbott's website, on a paged titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for

infants who aren't breastfed—for medical reasons or otherwise—**infant formula is the only appropriate, safe alternative** to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

36. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

37. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature

babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and "Includes expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of **breast milk research** and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive **breast milk studies** to date" (emphasis added).

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free formula, coupons, and even entire gift baskets to parents in hospitals, medical clinics, and residential charities where out-of-town families stay while their babies receive long-term treatment in the NICU.

40. Through this early targeting, Defendants create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for Defendants. Defendants' gift baskets send confusing signals to mothers who are

simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

41. Further, when Defendants recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:

42. Defendants have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider Defendants' cow's milk-based products a first choice. This marketing scheme is employed despite Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like Baby Theodore.

Defendants' Inadequate Warnings

43. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

44. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

45. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Enfamil's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

46. Mead cites no medical literature or research to guide the use of its products.

47. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

48. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

49. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

51. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

52. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

53. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical

professionals or hospitals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Safer Alternative Designs

55. Defendants' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. Defendants could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

56. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

57. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against All Defendants)

58. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

59. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

60. Abbott and Mead also owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for the intended use.

61. Abbott and Mead knew that their products would be used to feed premature infants like Baby Theodore and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

62. Baby Theodore ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to Baby Theodore outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

63. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that Defendants' products do.

64. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

65. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

66. Abbott's and/or Mead's products were fed to Baby Theodore, which directly and proximately caused his NEC and led to his death.

67. As a further direct result, Plaintiffs incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Their lives have been significantly affected by Baby Theodore's injuries and death.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against All Defendants)

68. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

69. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

70. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

71. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like Baby Theodore, and that their products might cause those infants to develop NEC, severe injury, or death, yet it failed to provide adequate warnings of those risks. Among other risks, Defendants:

a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failed to warn that cow's milk-based products are unsafe and/or contra-indicated for premature infants like Baby Theodore; and/or

c. Carried warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to carry a large and prominent black box-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Defendants' products, notwithstanding their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the baby's parents; and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

72. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

73. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of their products, Baby Theodore was fed cow's milk-based products, which caused him to develop NEC.

74. The unwarned of risks are not of a kind that an ordinary consumer would expect. Had physicians and healthcare providers known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed Baby Theodore those products. Had Plaintiffs known of the significant risks of feeding Baby Theodore cow's milk-based formula, they would not have allowed such products to be fed to Baby Theodore.

75. As a further direct result, Plaintiffs incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Their lives have been significantly affected by Baby Theodore 's injuries and death.

COUNT III: NEGLIGENCE
(Against All Defendants)

76. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

77. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

78. At all times relevant to this action, Baby Theodore's healthcare providers used the products at issue in their intended manner and for their intended purpose.

79. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's

milk-based infant products at issue in this litigation and thereby breached their duty to the general public and Plaintiffs.

80. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contra-indicated for premature infants like Baby Theodore; and/or

c. Carrying warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to carry a large and prominent black box-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Defendants' products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach the baby's parents; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

81. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

82. As a direct and proximate result of Defendants' failure to act in a reasonably prudent manner and their breach of duty, Baby Theodore was fed cow's milk-based products, which caused him to develop NEC.

83. Had Abbott and Mead satisfied their duties to the consuming public in general, Baby Theodore would not have been exposed to their unreasonably dangerous cow's milk-based products.

84. As a further direct result, Plaintiffs incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Plaintiffs' lives have been significantly affected by Baby Theodore 's injuries and death.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against All Defendants)

85. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

86. At all times relevant to this action, Baby Theodore (and his caretakers) used the products at issue in their intended manner and for their intended purpose.

87. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

88. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

89. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Theodore was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

90. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

91. Defendants' misrepresentations were intended to, and in fact did, induce hospitals and healthcare providers, including Baby Theodore's hospital and healthcare providers, to provide their infant products to babies, including to Baby Theodore.

92. Plaintiffs were not aware that these misrepresentations were false and justifiably relied on them. Defendants' misrepresentations induced Plaintiffs to allow Baby Theodore to be fed Abbott's and/or Mead's infant products, in reliance on all the messaging she received about formula feeding, including, directly or indirectly, Defendants' messaging. Had Abbott and Mead not committed these intentional misrepresentations, Baby Theodore would not have been exposed to their unreasonably dangerous cow's milk-based products.

93. As a direct and proximate result, Abbott's and/or Mead's products were fed to Baby Theodore causing his NEC and the subsequent health impacts and death.

94. As a further direct result, Plaintiffs have incurred medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Plaintiffs' lives have been significantly affected by Baby Theodore 's injuries and death.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against All Defendants)

95. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

96. At all times relevant to this action, Baby Theodore used the products at issue in their intended manner and for their intended purpose.

97. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

98. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

99. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time Baby Theodore was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were

unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

100. Abbott and Mead were negligent or careless in not determining those representations to be false.

101. Defendants' misrepresentations were intended to and did in fact induce hospitals and healthcare providers, including Baby Theodore's hospital and healthcare providers, to provide their products to babies, including to Baby Theodore.

102. Defendants' misrepresentations induced, and were intended to induce, Plaintiffs to allow Baby Theodore to be fed Abbott's and/or Mead's infant products, in justifiable reliance on all the messaging received about formula feeding, including, directly or indirectly, Defendants' messaging. Had Abbott and Mead not committed these negligent misrepresentations, Baby Theodore would not have been exposed to their unreasonably dangerous cow's milk-based products.

103. As a direct and proximate result, Abbott's and/or Mead's products were fed to Baby Theodore, causing his NEC and the subsequent health impacts and death.

104. As a further direct result, Plaintiffs incurred medical expenses and suffered significant emotional distress, loss of income, and other harms. Plaintiffs' lives have been significantly affected by Baby Theodore's injuries, and related expenses.

COUNT VI: BREACH OF EXPRESS WARRANTY
(Against All Defendants)

105. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

106. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed infant products as herein above described that was fed to Baby Theodore.

107. At all relevant times, Defendants expressly warranted to Baby Theodore's Parents, and LAC + USC Medical Center, that their baby products were safe for ingestion by preterm

infants such as Baby Theodore.

108. At all relevant times, Defendants expressly warranted to Baby Theodore's Parents, and LAC + USC Medical Center, that the effectiveness of their infant products outweighed any potential dangers and/or risks.

109. The aforementioned express warranties were made to Baby Theodore's Parents, and LAC + USC Medical Center, by way of Abbott and Mead's labels, direct advertisement and/or marketing.

110. Upon information and belief, the aforementioned express warranties were made to Baby Theodore's Parents' physicians by way of Abbot and Meade's labels, information from Defendants' sales advertising and promotional materials.

111. Upon information and belief, the healthcare providers at LAC + USC Medical Center, obtained the information regarding the efficacy and safety of Defendants' infant products from their labels.

112. Upon information and belief, Defendants expressly warranted to the healthcare providers at LAC + USC Medical Center by way of the product's label that their infant products were safe for ingesting by infants such as Baby Theodore.

113. On or about September 9, 2021 through November 22, 2022, when Baby Theodore's Parents permitted, LAC + USC Medical Center to use Defendants' infant products and throughout Baby Theodore's ingestion of said products, Defendants expressly warranted to them, by way of the product's label, that their infant products were safe and effective.

114. On or about September 9, 2021 through November 22, 2022, when Baby Theodore's Parents permitted, LAC + USC Medical Center to use Defendants' infant products and throughout Baby Theodore's ingestion of said products, Defendants expressly warranted to

Plaintiffs, by way of the product's label, that their infant products were safe for infant ingestion.

115. As a result of Defendants' express warranties to the LAC + USC Medical Center, physicians were induced to recommend feeding Baby Theodore Defendants' infant products, and Baby Theodore's Parents were induced to permit Baby Theodore's ingestion of said infant products from September 2021 through November 2022.

116. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Baby Theodore's Parents, would permit the use and/or ingestion of said infant products based upon their express warranties.

117. At all relevant times, Defendants reasonably anticipated and expected that healthcare workers, such as Baby Theodore's healthcare providers at LAC + USC Medical Center would recommend and/or dispense said infant products based upon their express warranties.

118. At all relevant times, Abbott and Mead knew or reasonably should have known that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death.

119. At all relevant times, Abbott and Mead knew or reasonably should have known that their cow's milk-based products were not safe for ingestion by preterm infants such as Baby Theodore.

120. At all relevant times, Defendants knew or should have known that their cow's milk-based products were unreasonably dangerous because the safety risk outweighed any benefit of other nutrition options available.

121. The unreasonably dangerous characteristics of these cow's milk-based products were beyond that which would be contemplated by the ordinary user, such as Baby Theodore's Parents, with the ordinary knowledge common to the public as to the said infant product's

characteristics and safety.

122. The unreasonably dangerous characteristics of cow's milk-based products were beyond that which would be contemplated by Baby Theodore's healthcare providers, with the ordinary knowledge common to the public as to the cow's milk-based product's characteristics.

123. At the time the cow's milk-based infant products left the Defendants' control, these products did not conform to Defendants' express warranties because they were not safe to use as a source for preterm infants, in that they were associated with NEC, severe injury, or death,

124. At the time the cow's milk-based infant formulas left the Defendants' control, these cow's milk-based infant formulas did not conform to Defendants' express warranties because the effectiveness of said cow's milk-based formulas does not outweigh any of the dangers and/or risks associated with the use of these formulas in preterm infants.

125. The express warranties made by Defendants regarding the safety and efficacy of cow's milk-based infant formula were made with the intent to induce Baby Theodore's Parents to use the product and/or Baby Theodore's healthcare providers, LAC + USC Medical Center to dispense the product.

126. Defendants knew and/or should have known that by making the express warranties to Baby Theodore's Parents and/or Baby Theodore's healthcare providers, LAC + USC Medical Center, it would be the natural tendency of Plaintiffs to use cow's milk-based infant formula and/or Baby Theodore's healthcare providers to recommend feeding preterm infants cow's milk-based formula.

127. Plaintiffs and Baby Theodore's healthcare providers, LAC + USC Medical Center, as well as members of the medical community, relied on the express warranties of the Defendants identified herein.

128. The express warranties made by Defendants regarding the safety and efficacy of cow's milk-based infant formula induced Baby Theodore's Parents to use the product in feeding Baby Theodore and/or Baby Theodore's healthcare providers to recommend using the product.

129. Plaintiffs and Baby Theodore 's catastrophic injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties.

130. Plaintiffs and Baby Theodore's catastrophic injuries and damages arose from a reasonably anticipated use of the products by Baby Theodore's Parents and ingestion of the products by Baby Theodore.

131. Accordingly, Defendants are liable as a result of their breach of express warranties to Baby Theodore's Parents and Baby Theodore.

132. As a result of the foregoing breaches, Baby Theodore's Parents were caused to incur medical expenses and suffered significant emotional distress, loss of income, loss of consortium, and other harms. Baby Theodore was caused to incur catastrophic injuries including NEC and death.

133. By reason of the foregoing, Baby Theodore's Parents and Baby Theodore have been severely and catastrophically injured. As a result of the foregoing acts and omissions the Baby Theodore's Parents require and/or will require more heath care and services and did incur medical, health, incidental, and related expenses.

COUNT VII: BREACH OF IMPLIED WARRANTIES
(Against All Defendants)

134. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

135. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendants who

designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed cow's milk-based infant formula as hereinabove described that was used by Plaintiffs and Baby Theodore.

136. At the time Defendants marketed, sold, and distributed cow's milk-based infant formula for use by Plaintiffs and Baby Theodore, Defendants knew of the use for which cow's milk-based infant formula and impliedly warranted the product to be of merchantable quality and safe and fit for ordinary use.

137. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Baby Theodore's Parents and Baby Theodore, would use and/or consume cow's milk-based infant formula for the infant's nutrition.

138. At all relevant times, Defendants reasonably anticipated and expected that healthcare providers, such as Baby Theodore's providers, LAC + USC Medical Center, would dispense cow's milk-based infant formula for the feeding of preterm infants such as Baby Theodore.

139. At all relevant times, Defendants impliedly warranted to Baby Theodore's Parents, Baby Theodore 's healthcare providers, LAC + USC Medical Center, and the medical community that cow's milk-based infant formula was of merchantable quality and safe and fit for ordinary use in that it was safe to feed preterm infants such as Baby Theodore.

140. At all relevant times, Defendants impliedly warranted to Baby Theodore's Parents, Baby Theodore's healthcare providers, LAC + USC Medical Center, and the medical community that cow's milk-based infant formula was of merchantable quality and safe and fit for ordinary use in that it was effective to use as a food source for preterm infants such as Baby Theodore.

141. At all relevant times, Defendants impliedly warranted to Baby Theodore's Parents,

Baby Theodore's healthcare providers, LAC + USC Medical Center, and the medical community that cow's milk-based infant formula was of merchantable quality and safe and fit for ordinary use in that the effectiveness of cow's milk-based infant formula outweighed any potential dangers and/or risks.

142. At all relevant times, Defendants knew or should have known that cow's milk-based infant formula was unreasonably dangerous because of its increased risk of causing NEC, serious injury, and death when used in the form and manner as provided by Defendants.

143. At all relevant times, Defendants knew or should have known that cow's milk-based formula was unreasonably dangerous because its safety risk outweighed any efficacy the formula may have.

144. The unreasonably dangerous characteristics of cow's milk-based infant formula were beyond that which would be contemplated by the ordinary user such as Baby Theodore's Parents, with the ordinary knowledge common to the public as to the product's characteristics.

145. The unreasonably dangerous characteristics of cow's milk-based infant formula were beyond that which would be contemplated by healthcare providers, such as Baby Theodore's healthcare providers, LAC + USC Medical Center, with the ordinary knowledge common to the public as to the product's characteristics.

146. At all relevant times and at the time cow's milk-based infant formula left the Defendants' control, the implied warranties made by Defendants were false, misleading, and inaccurate because cow's milk-based infant formula was not safe to use as a food source for preterm infants such as Baby Theodore, in that it carried with it an increased risk of NEC, serious injury, and death.

147. At all relevant times and at the time cow's milk-based infant formula left the

Defendants' control, the implied warranties made by Defendants were false, misleading and inaccurate because the effectiveness of cow's milk-based infant formula did not outweigh any the dangers and/or risks associated with these formulas in feeding preterm infants such as Baby Theodore.

148. Baby Theodore's Parents relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to cow's milk-based infant formula.

149. Baby Theodore's Parents reasonably relied upon the skill and judgment of Defendants as to whether cow's milk-based infant formula was of merchantable quality and safe and fit for its intended use.

150. Upon information and belief, Baby Theodore's healthcare providers, LAC + USC Medical Center, relied on Defendants' implied warranties of merchantability and fitness for the ordinary use and purpose relating to cow's milk-based infant formula.

151. Upon information and belief, Baby Theodore's healthcare providers, LAC + USC Medical Center, reasonably relied upon the skill and judgment of Defendants as to whether cow's milk-based infant formula was of merchantable quality and safe and fit for its intended use.

152. Cow's milk-based infant formula was introduced into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

153. Defendants herein breached the aforesaid implied warranties, as their cow's milk-based infant formula was not merchantable nor fit for its intended purposes and uses.

154. Baby Theodore's Parents would not have used cow's milk-based infant formula

and/or, upon information and belief, Baby Theodore's healthcare providers, LAC + USC Medical Center, would not have provided cow's milk-based infant formula but for the aforesaid implied warranties.

155. Baby Theodore's Parents and Baby Theodore's injuries and damages were directly caused by Defendants' breach of the aforementioned implied warranties.

156. Baby Theodore's Parents and Baby Theodore 's injuries and damages arose from a customary, usual, reasonably foreseeable use of the product by the Plaintiffs.

157. As a result of the foregoing breaches, Baby Theodore was caused to suffer serious and dangerous injuries including NEC and death, and Baby Theodore's Parents were caused to suffer other severe and personal injuries which are permanent and lasting in nature, physical and mental anguish, including diminished enjoyment of life.

COUNT VIII: LOSS OF CONSORTIUM
(Against All Defendants)

158. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

159. Loss of filial consortium is a derivative claim. It is derivative of each of the claims and allegations above.

160. At all relevant times Plaintiffs Zaira Rios and Martin Rios were Baby Theodore's lawful parents.

161. As a result of Defendants' tortious conduct, Plaintiffs suffered a loss of affection, companionship, society, and consortium of their child.

COUNT IX: SURVIVAL ACTIONS
(Against All Defendants)

162. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set

forth herein.

163. Plaintiffs, as parents and proposed representatives of Baby Theodore and his estate, are entitled to damages for the harms inflicted upon the decedent, as provided under applicable state law.

COUNT X: WRONGFUL DEATH ACTIONS
(Against All Defendants)

164. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

165. Plaintiffs, as parents and proposed representatives of Baby Theodore and his estate, are entitled to damages for the harms inflicted upon the decedent, and for the harms inflicted upon them, as provided under applicable state law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

1. For compensatory damages in an amount to be proven at trial;

2. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, loss of consortium, and other non-economic losses sustained as a result of Defendants' conduct;

3. For past, present, and future out-of-pocket costs, lost income and/or lost revenue and/or lost profits and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

4. For interest as permitted by law;

5. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

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6. For such other and further relief as the Court deems proper.

Dated: March 31, 2023

Respectfully submitted,

ROBINSON CALCAGNIE, INC.

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Attorneys for Plaintiffs

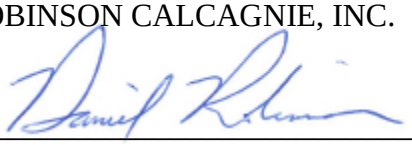
DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims triable.

Dated: March 31, 2023

Respectfully submitted,

ROBINSON CALCAGNIE, INC.



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